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10/526,221	11/15/2005	Paulo Cavalcanti Gomes Ferreira	265833US0X PCT	8194

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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/526,221	FERREIRA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24 and 30-37* is/are pending in the application.

4a) Of the above claim(s) *15,30-33,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-24,34 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *51705*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14, 16-24 and 34-35, drawn to a method comprising increasing by recombinant means expression in a plant or plant part of a cdc27a nucleic acid sequence, a plant, plant part, and a genetic construct, in the reply filed on January 22, 2008 is acknowledged.

The traversal is on the ground(s) that the Examiner did not indicate that she interpreted the contents of the claims in the light of the description when making her assertion regarding the technical feature.

This is not found persuasive because the specification explicitly supports the assertion that the technical feature linking the inventions is increasing or decreasing expression in a plant or plant part of a cdc27a nucleic acid sequence and/or increasing or decreasing levels and/or activity in a plant of a CDC27A protein, and that increasing or decreasing expression in a plant or plant part of a cdc27a nucleic acid sequence and/or increasing or decreasing levels and/or activity in a plant of a CDC27A protein is obvious or anticipated over WO 01/02430 and therefore does not constitute a special technical feature as defined by PCT Rule 13.2 because it does not define a contribution over the prior art.

See, for example, the abstract which states "A method to change development of a plant or plant part, when compared to the wild-type plant or plant part, by increasing or decreasing expression in a plant or plant part of a cdc27a nucleic acid sequence and/or increasing or decreasing levels and/or activity in a plant of a CDC27A protein", and at the paragraph spanning pages 2-3, which states that "The isolation and characterization of

a cdc27a gene from Arabidopsis thaliana was described in international patent application WO0102430. In WO0102430 there is disclosed the use of cdc27a muteins or the down-regulation of cdc27 to cause a malfunction of the APC complex and to cause endoreduplication via stimulation of DNA synthesis and/or blockage of mitosis."

Accordingly, claims 15, 30-33 and 36-37, and the nonelected subject matter recited in claims 1-14, 16-24 and 34-35, are withdrawn from consideration

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 1-14, 16-24 and 34-35 are objected to because of the following informalities: the claims are directed in part to nonelected subject matter. Appropriate correction is required.

Claims 1-14, 17-24 and 34-35 are objected to because of the following informalities: the claims lack an initial article. Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: the brief description of Figure 6 states that "FIG. 6 is the nucleic acid sequence and protein sequence of the Arabidopsis thaliana cdc27A proteins useful for the methods of the present invention", yet Figure 6 also illustrates sequences from Oryza sativa, Saccharum sp., Zea mays, Sorghum bicolor and Triticum aestivum. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16-24 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method comprising increasing by recombinant means the expression in a plant or plant part of a cdc27a nucleic acid sequence, including a method comprising introducing into a plant a nucleic acid sequence capable of increasing expression of a cdc27a gene, a method wherein said nucleic acid sequence is a cdc27a nucleic acid, a method wherein said nucleic acid is from a dicotyledonous plant, a method wherein said nucleic acid sequence is an allelic variant of a cdc27a nucleic acid sequence, a method wherein said nucleic acid sequence is a splice variant of a cdc27a nucleic acid sequence, a method wherein said nucleic acid sequence is introduced in a sense direction into a plant, a method wherein expression of said nucleic acid is driven by a constitutive promoter, and a method comprising the introduction into a plant of a construct comprising, a nucleic acid sequence capable of increasing expression of a cdc27a nucleic acid one or more control sequence capable of regulating expression of the nucleic acid sequence in a plant. The claims are also drawn to a plant, plant part, and a genetic construct.

With respect to a nucleic acid sequence capable of increasing expression of a cdc27a gene, the specification describes a single type of nucleic acid sequence, a cdc27a nucleic acid encoding a CDC27a protein. The specification does not describe other types of nucleic acid sequences capable of increasing expression of a cdc27a gene.

With respect to a cdc27a nucleic acid, the specification describes two full-length cdc27a nucleic acid sequences obtained from *Arabidopsis thaliana* (SEQ ID NO:1 and SEQ ID NO:3) that encode CDC27a proteins (SEQ ID NO:2 and SEQ ID NO:4) (Figure 6 and sequence listing). The specification also discloses that tobacco plants transformed with an expression vector comprising SEQ ID NO:1 in a sense orientation develop at a faster rate, show increased biomass, show earlier flowering, have more flowers, and are taller at the time of flowering, as compared to control tobacco plants (pages 34-38).

The specification also describes five partial cdc27a nucleic acids that were isolated from rice (SEQ ID NO 5), from sugar cane (SEQ ID NO 7), from maize (SEQ ID NO 9), from sorghum (SEQ ID NO 11) and from wheat (SEQ ID NO 13) (Figure 6 and sequence listing). The specification does not, however, describe or characterize the function of these five partial cdc27a nucleic acids.

With respect to a nucleic acid sequence is an allelic variant of a cdc27a nucleic acid sequence or a splice variant of a cdc27a nucleic acid sequence, the specification does not describe the structure of any such nucleic acid sequence.

The Federal Circuit has clarified the application of the written description requirement to nucleic acid sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of

structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and/or uncharacterized nucleic acid sequences that are capable of increasing expression of a cdc27a gene, nor the structural features unique to the genus. Applicant also has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and/or uncharacterized cdc27a nucleic acid sequences that are useful when their expression is increased in a plant or plant part, nor the structural features unique to the genus.

Claims 1-14, 16-24 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising introducing into a plant in a sense direction a cdc27nucleic acid sequence having a sequence of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for methods comprising introducing into a plant other nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method comprising increasing by recombinant means the expression in a plant or plant part of a cdc27a nucleic acid sequence, including a method comprising introducing into a plant a nucleic acid sequence capable of

increasing expression of a cdc27a gene, a method wherein said nucleic acid sequence is a cdc27a nucleic acid, a method wherein said nucleic acid is from a dicotyledonous plant, a method wherein said nucleic acid sequence is an allelic variant of a cdc27a nucleic acid sequence, a method wherein said nucleic acid sequence is a splice variant of a cdc27a nucleic acid sequence, a method wherein said nucleic acid sequence is introduced in a sense direction into a plant, a method wherein expression of said nucleic acid is driven by a constitutive promoter, and a method comprising the introduction into a plant of a construct comprising a nucleic acid sequence capable of increasing expression of a cdc27a nucleic acid one or more control sequence capable of regulating expression of the nucleic acid sequence in a plant. The claims are also drawn to a plant, plant part, and a genetic construct.

The specification discloses that tobacco plants transformed with an expression vector comprising SEQ ID NO:1 in a sense orientation develop at a faster rate, show increased biomass, show earlier flowering, have more flowers, and are taller at the time of flowering, as compared to control tobacco plants (pages 34-38).The specification does not disclose the effect of expressing in plants other nucleic acid sequences.

The full scope of the claimed invention is not enabled because the effect of expressing in a plant a nucleic acid encoding CDC27 homologue is unpredictable, since CDC27 homologues may have structural and functional differences as well as similarities, and since a single plant species may natively comprise more than one type of cdc27 gene.

See, for example, Perez-Perez J.M. et al. (Specialization of CDC27 function in the *Arabidopsis thaliana* anaphase-promoting complex (APC/C). Plant J. 2008 Jan;53(1):78-

89. Epub 2007 Oct 17), who investigated the specialization of the two *Arabidopsis* CDC27 subunits (HBT/CDC27B and CDC27A) in the anaphase-promoting complex (APC/C). Perez-Perez J.M. et al. teach that while the phenotypes of weak and null hobbit (hbt) alleles indicate a primary role for HBT/CDC27B in the control of post-embryonic cell division and cell elongation, cdc27a null alleles are phenotypically indistinguishable from the wild type, and cdc27a hbt double-mutant gametes are non-viable, indicating a redundant requirement for both CDC27 subunits during gametogenesis (abstract; Table 1a; page 80 column 2; page 85 column 2). Perez-Perez J.M. et al. also teach that their data suggest that both proteins are redundantly required for the full APC/C function during cell cycle progression, but that HBT/CDC27 is essential to drive cell division-associated post-embryonic growth. (page 85 column 2)

In the instant case, the specification does not provide sufficient guidance with respect to which nucleic acids other than a cdc27nucleic acid sequence having a sequence of SEQ ID NO:1 or encoding SEQ ID NO:2 will increase the expression of a cdc27a nucleic acid in a plant cell and produce a predictable result. Absent such guidance one skilled in the art would have to screen a variety of different types of nucleic acids for their ability to increase the expression of a cdc27a nucleic acid in a plant cell, and then further determine their effect when expressed in a plant transformed therewith in order to identity other nucleic acids that will increase the expression of a cdc27a nucleic acid in a plant cell and produce a predictable result. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 1 and 2 require increasing by recombinant means expression in a plant or plant part of a cdc27a nucleic acid sequence, but the claims recite no positive method steps by which this may be accomplished.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is indefinite because there is insufficient antecedent basis for "the nucleic acid sequence of (i)" recited in line 7.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is indefinite because there is insufficient antecedent basis for "the nucleic acid sequence of (i)" recited in line 6.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-14, 16-24 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemerly A. et al. (WO 01/02430, published 11 January 2001).

The claims are drawn to a method to change development of a plant or plant part or for the production of a transgenic plant having changed development said method comprising increasing by recombinant means the expression in a plant or plant part of a cdc27a nucleic acid sequence, including a method comprising introducing into a plant a nucleic acid sequence capable of increasing expression of a cdc27a gene, a method wherein said nucleic acid sequence is a cdc27a nucleic acid, a method wherein said nucleic acid is from a dicotyledonous plant, a method wherein said nucleic acid sequence is introduced in a sense direction into a plant, a method wherein expression of said nucleic acid is driven by a constitutive promoter, and a method comprising the introduction into a plant of a construct comprising a nucleic acid sequence capable of increasing expression of a cdc27a nucleic acid one or more control sequence capable of regulating expression of the nucleic acid sequence in a plant.

The claims are also drawn to a plant obtained by the claimed methods which plant has changed development, including a plant wherein said plant is a monocotyledonous plant, and/or wherein said plant is selected from rice, maize, wheat, barley, millet, soybean, leguminosae, rapeseed, sunflower, canola, alfalfa, sugarcane, popular, tobacco, and cotton, and including a plant part, propagule or progeny from a plant according to claim 17.

The claims are additionally drawn to a genetic construct comprising, a nucleic acid sequence capable of increasing expression of a cdc27a gene; one or more control sequence capable of regulating expression of the nucleic acid sequence in a plant, including a construct wherein said nucleic acid is a cdc27a nucleic from a dicotyledonous plant, including a construct wherein said control sequence is a constitutive promoter or at

least a part thereof, and to a plant or plant part having changed development and comprising said genetic construct.

Hemerly A. et al. teach a method comprising introducing into a plant a nucleic acid sequence that is a cdc27a nucleic acid obtained from the dicotyledonous plant *Arabidopsis thaliana*, including a method wherein said nucleic acid sequence is introduced in a sense direction into a plant, a method wherein expression of said nucleic acid is driven by a constitutive promoter, and a method comprising the introduction into a plant of a construct (pages 26-29; claims 15-16 and 22-26).

Hemerly A. et al. also teach plants obtained by their methods including monocotyledonous plants and plants such as rice, maize, wheat, barley, soybean, leguminosae, rapeseed, sunflower, canola, sugarcane, and cotton, and a plant part, propagule or progeny (pages 26-29; claims 15-16 and 22-26).

Hemerly A. et al. additionally teach drawn to a genetic construct comprising, a nucleic acid sequence that is a cdc27a nucleic acid obtained from the dicotyledonous plant *Arabidopsis thaliana* and one or more control sequence capable of regulating expression of the nucleic acid sequence in a plant, including a construct wherein said control sequence is a constitutive promoter or at least a part thereof, and a plant or plant part comprising said genetic construct (pages 26-29; claims 15-16 and 22-26).

The plants taught by Hemerly A. et al. have changed development in that DNA replication and mitosis are altered in their cells as a consequence of their transformation. Alternatively, the plants taught by Hemerly A. et al. have changed development since the recited changes in plant development are merely the end result of practicing the methods as claimed (see, for example, page 1 lines 1-4 of the specification). Accordingly Hemerly

A. et al. need not explicitly teach these limitations since they are inherent end results of producing plants using the methods as claimed.

Further, while Hemerly A. et al. do not explicitly teach that their methods are intended to change development of a plant or plant part or for the production of a transgenic plant having changed development, Hemerly A. et al. need not explicitly teach these limitations as the references to changing the development of a plant or plant part and the production of a transgenic plant having changed development recited in the claim preambles may be interpreted as intended uses of the claimed methods that are not specifically limiting. Alternatively, since the recited changes in plant development are merely the end result of practicing the methods as claimed (see, for example, page 1 lines 1-4 of the specification) Hemerly A. et al. need not explicitly teach these limitations since they are inherent end results of practicing the methods as claimed.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/
Primary Examiner, Art Unit 1638

CC